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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Upasani *et al.*

Appl. No.: 10/772,445

Filed: February 6, 2004

For: **Substituted Quinazolines and
Analogues and the Use Thereof**

Confirmation No.: 5165

Art Unit: 1615

Examiner: *To be assigned*

Atty. Docket: 1483.0340003/JMC/JSL

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of the documents were cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/654,839, filed September 1, 2000, now U.S. Patent No. 6,465,472 B1, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

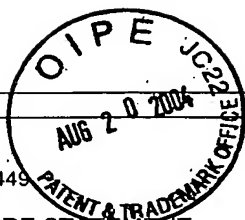
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Jeffrey S. Lundgren
Agent for Applicants
Registration No. 51,978

Date: Aug. 20, 2004

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1483.0340003/JMC/JSLAPPLICATION NO.
10/772,445FIRST NAMED INVENTOR
Upasani *et al.*FILING DATE
February 6, 2004ART UNIT
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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
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| | AA1 | 3,748,331 | 06/24/1973 | Cooke <i>et al.</i> | | | 05/06/1971 |
| | AB1 | 3,963,717 | 06/15/1976 | Cooke <i>et al.</i> | | | 03/10/1975 |
| | AC1 | 5,284,957 | 02/08/1994 | Huff | | | 09/03/1992 |
| | AD1 | 5,514,680 | 05/07/1996 | Weber <i>et al.</i> | | | 11/05/1993 |
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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|---------------------|-----|--------------------|------------|---------|-------|-----------|-------------|
| | AL1 | WO 94/13275 | 06/23/1993 | WIPO | | | Yes No |
| | AM1 | | | | | | Yes No |
| | AN1 | | | | | | Yes No |
| | AO1 | | | | | | Yes No |
| | AP1 | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | 1 | Anderson, B.A. <i>et al.</i> , "Application of a Practical Biocatalytic Reduction to an Enantioselective Synthesis of the 5H-2,3-Benzodiazepine LY300164," <i>J. Am. Chem. Soc.</i> 117:12358-12359, American Chemical Society (1995) |
| | AS | 1 | Buchan, A.M. <i>et al.</i> , "Delayed AMPA receptor blockade reduces cerebral infarction induced by focal ischemia," <i>Neuroreport</i> 2:473-476, Lippincott, Williams & Wilkins (1991) |
| | AT | 1 | Buchan, A.M. <i>et al.</i> , "AMPA Antagonists: Do They Hold More Promise for Clinical Stroke Trials Than NMDA Antagonists?" <i>Stroke Suppl. I</i> 24:I-148-I-154, Lippincott, Williams & Wilkins (1993) |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | <u>2</u> | Choi, D.W. et al., "Glutamate Neurotoxicity in Cortical Cell Culture," <i>J. Neurosci</i> 7:357-368, Society for Neuroscience (1987) |
| | AS | <u>2</u> | Coombs, R.V. et al., "Synthesis and Antiinflammatory Activity of 1-Alkyl-4-aryl-2(1H)-quinazolinones and Quinazolinethiones," <i>J. Med. Chem.</i> 16:1237-1245, American Chemical Society (1973) |
| | AT | <u>2</u> | Copani, A. et al., "Nootropic Drugs Positively Modulate γ -Amino-3-Hydroxy-5-Methyl-4-Isoxazolepropionic Acid-Sensitive Glutamate Receptors in Neuronal Cultures," <i>J. Neurochem.</i> 58:1199-1204, The International Society for Neurochemistry (1992) |

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| AS | <u>3</u> | Fetter, J. et al., "Electron Deficient Heteroaromatic Ammonioamidates-XVI," <i>Tetrahedron</i> 34:2557-2563, Pergamon Press (1978) |
| AT | <u>3</u> | Graham, S.H. et al., "A Dose-Response Study of Neuroprotection Using the AMPA Antagonist NBQX in Rat Focal Cerebral Ischemia," <i>J. Pharm. Exp. Ther.</i> 276:1-4, American Society for Pharmacology and Experimental Therapeutics (1996) |

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| AS | <u>4</u> | Houlihan, W.J. et al., "Antiinflammatory Properties of 8-Aryl-5-isopropyl-2H-1,3-dioxolo[4,5-g]quinazolin-6(5H)-ones and -thiones," <i>J. Med. Chem.</i> 25:1110-1113, American Chemical Society (1982) |
| AT | <u>4</u> | Hunter, J.C. and L. Singh, "Role of excitatory amino acid receptors in the mediation of the nociceptive response to formalin in the rat," <i>Neurosci Lett.</i> 174:217-221, Elsevier Scientific Publishers (1994) |

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| | AR | <u>5</u> | Ikeda, A. et al., "Clinical Trial of Piracetam in Patients with Myoclonus: Nationwide Multiinstitution Study in Japan," <i>Movement Disorders</i> 11:691-700, Raven Press (1996) |
| | AS | <u>5</u> | Iwasaki, Y. et al., "CNQX prevents spinal motor neuron death following sciatic nerve transection in newborn rats," <i>J. Neurosci.</i> 134:21-25, Society for Neuroscience (1995) |
| | AT | <u>5</u> | Jones, B.J. et al., "The potential anxiolytic activity of GR38032F, a 5-HT ₃ -receptor antagonist," <i>Br. J. Pharmacol.</i> 93:985-993, Macmillan Journals Ltd. (1988) |

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| | AR | <u>6</u> | Keana, J.F.W. et al., "Synthesis and Structure-Activity Relationships of Substituted 1,4-Dihydroquinoxaline-2,3-diones: Antagonists of N-Methyl-D-aspartate (NMDA) Receptor Glycine Sites and Non-NMDA Glutamate Receptors," <i>J. Med. Chem.</i> 38:4367-4379, American Chemical Society (1995) |
| | AS | <u>6</u> | Larson, J. et al., "Effects of an AMPA receptor modulator on methamphetamine-induced hyperactivity in rats," <i>Brain Res.</i> 738:353-356, Elsevier/North-Holland Biomedical Press (1996) |
| | AT | <u>6</u> | Le Peillet, E. et al., "The non-NMDA antagonists, NBQX and GYKI 52466, protect against cortical and striatal cell loss following transient global ischaemia in the rat," <i>Brain Res.</i> 571:115-120, Elsevier/North-Holland Biomedical Press (1992) |

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| | AS | <u>1</u> | McDonald, J.W. et al., "Physiological and pathophysiological roles of excitatory amino acids during central nervous system development," <i>Brain Res. Rev.</i> 15:41-70, Elsevier Science (1990) |
| | AT | <u>1</u> | Pelletier, J.C. et al., "Substituted 1,2-Dihydrophthalazines: Potent, Selective, and Noncompetitive Inhibitors of the AMPA Receptor," <i>J. Med. Chem.</i> 39:343-346, American Chemical Society (1996) |

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| | AR | <u>8</u> | Sang, C.N. et al., "Analgesic Effects of AMPA/Kainate Antagonist LY293558 in Human: Reduction of Capsaicin-Evoked Allodynia and Hyperalgesia But Not Pain Sensations In Normal Skin," <i>Soc. Neurosci</i> 23:1015, Abstract No. 401.14, Society of Neuroscience (October 1997) |
| | AS | <u>8</u> | Schoepp, D. et al., "Pharmacological and functional characteristics of metabotropic excitatory amino acid receptors," <i>Trends Pharm Sci</i> 11:508-515, Elsevier in Association with the International Union of Pharmacology (1990) |
| | AT | <u>8</u> | Sheardown, M.J. et al., "2,3-Dihydroxy-6-nitro-7-sulfamoyl-benzo(F)quinoxalin: A Neuroprotectant for Cerebral Ischemia," <i>Science</i> 247:571-574, American Association for the Advancement of Science (1990) |

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| | AR | <u>9</u> | Sheardown, M.J. et al., "AMPA, but not NMDA, receptor antagonism is neuroprotective in gerbil global ischaemia, even when delayed 24 h," <i>Eur. J. Pharmacol.</i> 236:347-353, Elsevier Science (1993) |
| | AS | <u>9</u> | Staubli, U. et al., "Facilitation of glutamate receptors enhances memory," <i>Proc. Natl. Acad. Sci. USA</i> 91:777-781, National Academy of Sciences (1994) |
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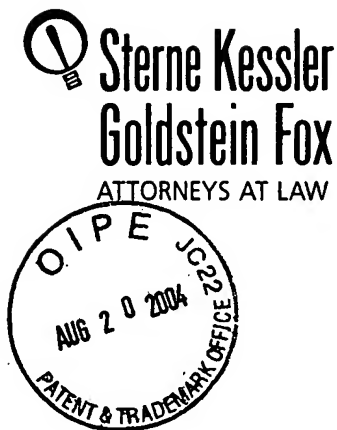
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| | AR | <u>10</u> | Woodward, R.M. et al., "In Vitro Pharmacology of ACEA-1021 and ACEA-1031: Systemically Active Quinoxalinediones with High Affinity and Selectivity for N-Methyl-D-aspartate Receptor Glycine Sites," <i>Mol. Pharmacol.</i> 47:568-581, American Society for Pharmacology and Experimental Therapeutics (1995) |
| | AS | <u>10</u> | Wrathall, J.R. et al., "Amelioration of Functional Deficits from Spinal Cord Trauma with Systemically Administered NBQX, an Antagonist of Non-N-Methyl-D-Aspartate receptors," <i>Exp. Neurology</i> 137:119-126, Academic Press (1996) |
| | AT | | |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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*Practice Limited to
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August 20, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1615

Re: U.S. Utility Patent Application
Application No. 10/772,445; Filed: February 6, 2004
For: **Substituted Quinazolines and Analogs and the Use Thereof**
Inventors: Upasani *et al.*
Our Ref: 1483.0340003/JMC/JSL

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 citing documents on Information Disclosure Statement (AA1-AD1, AL1, AR1-AT1, AR2-AT2, AR3-AT3, AR4-AT4, AR5-AT5, AR6-AT6, AR7-AT7, AR8-AT8, AR9-AT9, AR10, AS10);
3. First Supplemental Information Disclosure Statement;
4. Form PTO-1449 citing documents on First Supplemental Form PTO-1449 citing documents (AE1-AH1, AM1-AP1, AT10, AL2);
5. Second Supplemental Information Disclosure Statement;
6. Form PTO-1449 citing documents on Second Supplemental Form PTO-1449 citing documents (AM2, and AR11-AT11); and
7. Return Postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
August 20, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Jeffrey S. Lundgren
Agent for Applicants
Registration No. 51,978

JSL/asl
Enclosures

301903v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Upasani *et al.*

Appl. No.: 10/772,445

Filed: February 6, 2004

For: **Substituted Quinazolines and
Analogues and the Use Thereof**

Confirmation No.: 5165

Art Unit: 1615

Examiner: *To be assigned*

Atty. Docket: 1483.0340003/JMC/JSL

First Supplemental Information Disclosure Statement

Under 37 C.F.R. § 1.97(b)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering of this First Supplemental Information Disclosure Statement is a continuation of Applicants' Information Disclosure Statement filed herewith, in connection with the above-captioned application.

Copies of documents AE1 to AH1, AM1 to AL2, and AT10 were cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/654,839, filed September 1, 2000, now U.S. Patent No. 6,465,472 B1, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document AN1 cited on Form PTO 1449:

Document AN1 is in a foreign language. An English language abstract of document AN1 is attached as document AT10.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Jeffrey S. Lundgren
Agent for Applicants
Registration No. 51,978

Date: Aug. 20, 2004

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|---|-----|--------------------|--|---|-----------------|-------------------------------|-------------|
| FORM PTO-1449 | | | | ATTY. DOCKET NO. 1483.0340003/JMC/JSL | | APPLICATION NO. 10/772,445 | |
| FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT | | | | FIRST NAMED INVENTOR Upasani <i>et al.</i> | | | |
| | | | | FILING DATE February 6, 2004 | | ART UNIT 1516 | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
| | AA | | | | | | |
| | AB | | | | | | |
| | AC | | | | | | |
| | AD | | | | | | |
| | AE1 | 3,759,920 | 09/18/1973 | Linder <i>et al.</i> | | | 06/24/1971 |
| | AF1 | 3,856,960 | 12/24/1974 | Cooke <i>et al.</i> | | | 04/13/1973 |
| | AG1 | 4,224,328 | 09/23/1980 | Takesue | | | 04/11/1979 |
| | AH1 | 5,650,410 | 07/22/1997 | Sohda <i>et al.</i> | | | 04/17/1995 |
| | AI | | | | | | |
| | AJ | | | | | | |
| | AK | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
| | AL | | | | | | Yes No |
| | AM1 | DE 2 058 722 | 06/09/1971 | Germany | | | X Yes No |
| | AN1 | DE 2 307 808 | 08/30/1973 | Germany | | | Yes X No |
| | AO1 | GB 1341401 | 12/19/1993 | Great Britain | | | Yes No |
| | AP1 | EP 0 567 107 A1 | 10/27/1993 | Europe | | | Yes No |
| OTHER (Including Author, Title, Date, Pertinent Pages, etc.) | | | | | | | |
| | AR | | | | | | |
| | AS | | | | | | |
| | AT | <u>10</u> | Dialog File 351, Accession No. 1973-41080U/197329, Derwent WPI English language abstract for DE 2 307 808 (Document AN1) | | | | |
| EXAMINER | | | | | DATE CONSIDERED | | |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. | | | | | | | |

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| FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 1483.0340003/JMC/JSL | APPLICATION NO. 10/772,445 |
| | FIRST NAMED INVENTOR Upasani <i>et al.</i> | |
| | FILING DATE February 6, 2004 | ART UNIT 1516 |

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
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| | AA | | | | | | |
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| | AJ | | | | | | |
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FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|---------------------|-----|--------------------|------------|---------|-------|-----------|-------------|
| | AL2 | EP 0 634 169 A1 | 01/18/1995 | Europe | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
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| | AR | | |
| | AS | | |
| | AT | | |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Copy

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Upasani *et al.*

Appl. No.: 10/772,445

Filed: February 6, 2004

For: **Substituted Quinazolines and
Analogues and the Use Thereof**

Confirmation No.: 5165

Art Unit: 1615

Examiner: *To be assigned*

Atty. Docket: 1483.0340003/JMC/JSL

Second Supplemental Information Disclosure Statement

Under 37 C.F.R. § 1.97(b)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering of this Second Supplemental Information Disclosure Statement is a continuation of Applicants' First Information Disclosure Statement filed herewith, in connection with the above-captioned application.

Copies of the documents were cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 10/219,755, filed August 16, 2002, now U.S. Patent No. 6,765,006 B2, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document AM2 cited on Form PTO 1449:

Document AM2 is in a foreign language. An English language translation of document AM2 is attached as document AR11.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

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The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

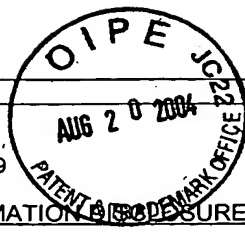
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| FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT | | | | ATTY. DOCKET NO. 1483.0340003/JMC/JSL | | APPLICATION NO. 10/772,445 | |
| | | | | FIRST NAMED INVENTOR Upasani <i>et al.</i> | | FILING DATE February 6, 2004 | |
| | | | | ART UNIT 1516 | | | |
| U.S. PATENT DOCUMENTS | | | | | | | |
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| | AA | | | | | | |
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| | AK | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
| | AL | | | | | | Yes No |
| | AM2 | JP S51-8287 | 01/23/1976 | Japan | | | X Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |
| OTHER (Including Author, Title, Date, Pertinent Pages, etc.) | | | | | | | |
| | AR | 11 | English language translation of Japanese Unexamined Patent Application No. JP S51-8287 published January 23, 1976, 7 pages. (Document AM2) | | | | |
| | AS | 11 | Yamamoto, M., et al., "Quinazolin-2-ones from 3,4-dihydroquinazolin-2-ones," <i>Chem. Abstr.</i> 84:586, Abstract No. 180277m, American Chemical Society (1976) | | | | |
| | AT | 11 | Supplementary Partial European Search Report for European Application No. EP99911063 filed on March 2, 1999 | | | | |
| EXAMINER | | | | | DATE CONSIDERED | | |
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